

Exhibit 11

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -
IN RE: ETHICON, INC. : MDL NO. 2327
PELVIC REPAIR SYSTEM, :
PRODUCTS LIABILITY :
LITIGATION :
- - -

THIS DOCUMENT RELATES TO ALL CASES

- - -
June 27, 2013
- - -

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Continued videotaped deposition of
PIET HINOUL, M.D., Ph.D. taken pursuant to notice,
was held at the law offices of Riker Danzig Scherer
Hyland & Perretti LLP, Headquarters Plaza, One
Speedwell Avenue, Morristown, New Jersey, beginning
at 9:19 a.m., on the above date, before Ann Marie
Mitchell, a Federally Approved Certified Realtime
Reporter, Registered Diplomate Reporter and Notary
Public for the State of New Jersey.

- - -
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1 to tissue during the removal process or other
2 complications related to the removal surgery.

3 Correct?

4 A. Yes. As with any surgery.

5 Q. You talked about earlier I believe
6 during your deposition that some patients will have
7 more major inflammatory reactions or -- strike that.

8 I think you testified earlier that
9 some patients will have more major inflammatory
10 reactions from the foreign body, the mesh, than
11 other patients; is that right?

12 MS. JONES: Object to the form.

13 THE WITNESS: Right. So the way
14 people respond to a foreign substance, it is like
15 allergies, it will differ. Certain people are
16 allergic, certain people are not, some of them are
17 severely allergic, some are not. So the way people
18 form a scar from a skin incision, it will differ.
19 And this is exactly the same what would happen to a
20 TVT or to a mesh product; scarring may differ from
21 one patient to another.

22 BY MR. CARTMELL:

23 Q. Has the company ever been able to
24 figure out which patients will have more major
25 severe reactions to the foreign body?

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1 A. No. I don't think. We as a company
2 have not been able to identify that, nor any
3 academic groups that we know of.

4 Q. Is degradation related to the TVT
5 products a potential complication?

6 MS. JONES: Object to the form.

7 THE WITNESS: Degradation of the
8 tape?

9 BY MR. CARTMELL:

10 Q. Yes.

11 A. No.

12 Q. Did Ethicon know at the time of the
13 launch that the TVT products, that some patients
14 would suffer complications making it impossible for
15 them to have comfortable sexual relations for the
16 rest of their lives?

17 MS. JONES: Object to the form.

18 THE WITNESS: It would have seemed
19 certainly very unlikely, but, again, theoretically,
20 it would have been a possibility.

21 BY MR. CARTMELL:

22 Q. The company knew that. Correct?

23 A. We anticipated those kinds of risks,
24 yes.

25 Q. And the company knew of the

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1 So you try to mitigate to prevent that. That
2 doesn't mean that it will ever occur or that it has
3 ever occurred.

4 Q. And so if we look at, for example,
5 the topic that says, "Degraded mesh leading to
6 bunching/wrinkling in mesh," has that been
7 confirmed, to your knowledge, that it actually
8 occurred leading to exposure?

9 A. Right. So to the best of my
10 knowledge, with more than a decade of use of these
11 products and longer, the mesh has never been shown
12 to degrade.

13 Q. If we look, then you were also asked
14 about the chart that relates to fistula formulation?

15 A. Yes.

16 Q. And would your answers be the same as
17 to the hazards that are listed under fistula
18 formulation -- formation? Let me clarify that.

19 I mean, my question is, has it been
20 confirmed that the conditions listed under "Hazards"
21 by fistula formulation actually occurred
22 specifically listed -- leading to fistula
23 formulation?

24 A. Formation. I think there's a big
25 difference between exposure and fistula formation,

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1 A. Correct.

2 Q. So if it had turned out over those
3 seven years or so that some of these hazards and
4 harms really didn't apply, you wouldn't have
5 included them. Right?

6 A. We have to include them, but they
7 would then get a frequency of zero or very low
8 frequency. That's why there is a frequency column
9 that we haven't discussed, but you will find all the
10 explanation for that on page 26.

11 Q. Now, you talked about the concept of
12 degradation of mesh. And since you did, I'm just
13 going to quickly identify a document and ask you a
14 question about it.

15 - - -

16 (Deposition Exhibit No. T-733,
17 PowerPoint, "Investigating Mesh Erosion in
18 Pelvic Floor Repair," 18 May 2011, Bates
19 stamped ETH.MESH.02589032 through
20 ETH.MESH.02589079, was marked for
21 identification.)

22 - - -

23 BY MR. SLATER:

24 Q. It's a document that's now being
25 marked as Exhibit 733. I promise you this is only

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1 going to take about two minutes, this document.

2 I've handed you what we've marked as
3 Exhibit T-733. And it's a report that was
4 commissioned for Johnson & Johnson and Ethicon for a
5 company named PA Consulting investigating mesh
6 erosion in pelvic floor dated May 18, 2011. Do you
7 see this? Do you see the document in front of you?
8 Correct?

9 A. Yes.

10 Q. What I'd like you to do is turn to
11 page 35.

12 And this company that was hired by
13 Johnson & Johnson to do this evaluation concluded
14 "Polypropylene can suffer from degradation following
15 implant." And it says just below that,
16 "Polypropylene has a long history of use but it is
17 subject to degradation; a process which initiates
18 after a few days post implantation in animal
19 studies." And then there's a citation 1 and there's
20 a reference. Do you see that below?

21 A. I see that, yes.

22 Q. And then a little further down,
23 actually at the very last bullet point, it says,
24 "High resolution images of excised meshes clearly
25 show physical degradation of polypropylene

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1 filaments." Do you see that?

2 A. Yes.

3 Q. And they're citing --

4 And when they talk about excised
5 meshes, they're talking about explants. Correct?

6 A. So yes.

7 Q. And they're citing "Images on file,
8 Prof. Bernd Klosterhalfen." Do you see that?

9 A. Yes.

10 Q. So PA Consulting, as part of this
11 study, consulted with Prof. Klosterhalfen according
12 to this study. Correct?

13 A. That's what you say. I don't know.

14 Q. And Prof. Klosterhalfen is probably
15 considered to be the pathologist with the most
16 knowledge in the world on the subject of what is
17 shown by explanted meshes in this field. Correct?

18 MS. JONES: Object to the form.

19 THE WITNESS: Prof. Klosterhalfen is
20 considered an expert in this field.

21 BY MR. SLATER:

22 Q. He's considered the foremost expert
23 in the field. Correct?

24 A. I don't know whether you can rank --
25 I don't know whether there is such a competition

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1 as...

2 Q. You certainly have referred to him as
3 the, quote/unquote, god of surgical pathology and
4 acknowledged to me that even though it was somewhat
5 of a tongue-in-cheek statement, it was a recognition
6 of his very high stature in the field. Correct?

7 A. Maybe it was ironic.

8 Q. Well, according to this study
9 commissioned by your company, they documented that
10 Prof. Klosterhalfen's own study of explanted meshes
11 showed physical degradation of the polypropylene
12 filaments. That's what's documented here. Correct?

13 MS. JONES: Object to the form.

14 THE WITNESS: No, because, you know,
15 all they refer to is an image on file. It's not a
16 study. Right? That's what it says.

17 BY MR. SLATER:

18 Q. This study, this document I've given
19 you, cites to Prof. Klosterhalfen's explant study as
20 evidence that excised meshes, explants, show
21 physical degradation of polypropylene filaments.
22 That was documented in Ethicon's and Johnson &
23 Johnson's records as of May 2011. Correct? You see
24 it in front of you. I'm not asking you for an
25 interpretation. That's what's documented. Correct?

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1 A. No, I disagree.

2 Q. You would disagree that the statement
3 says, "High resolution images of excised meshes
4 clearly show physical degradation of polypropylene
5 filaments"? You disagree that I've read the words
6 accurately?

7 A. Oh, you read perfectly well.

8 Q. And they cite to Prof. Klosterhalfen
9 as having shown them evidence to support that
10 statement. Correct?

11 MS. JONES: Object to the form.

12 BY MR. SLATER:

13 Q. That's what's stated right there.
14 Correct?

15 A. It -- why don't you read what is
16 stated as a reference.

17 Q. "Images on file, Prof. Bernd
18 Klosterhalfen." And then the fact that he's in
19 Aachen. I'm not going to try to pronounce the word.

20 A. I agree that that is what is written
21 there.

22 Q. So the idea of the mesh material as
23 documented in this FMEA actually being -- showing
24 degradation and causing complications as set forth
25 here described as harm in the FMEA table, there is

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1 evidence in Ethicon's files that that occurs and
2 I've just shown it to you. Correct?

3 MS. JONES: Object to the form.

4 THE WITNESS: No, no.

5 MR. SLATER: I have no other
6 questions.

7 MS. JONES: Let me follow up on that
8 one question.

9 - - -

10 EXAMINATION

11 - - -

12 BY MS. JONES:

13 Q. If you look back at Exhibit -- page
14 24 on Exhibit 722, under the "Exposure" chart?

15 A. Yes.

16 Q. Which says "Degraded mesh leading to
17 bunching/wrinkling in mesh"?

18 A. Yes.

19 Q. Have you ever seen that confirmed as
20 happening in women?

21 A. Absolutely not.

22 MS. JONES: Thank you.

23 - - -

24 EXAMINATION

25 - - -

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1 BY MR. SLATER:

2 Q. Just to be very clear, bunching and
3 wrinkling of mesh would be -- certainly bunching
4 would be synonymous with contraction of mesh.

5 Correct?

6 MS. JONES: Object to the form.

7 THE WITNESS: Not necessarily.

8 BY MR. SLATER:

9 Q. Well, certainly the terms are used
10 interchangeably by certain people. Correct?

11 A. I would also disagree with that. I
12 think bunching is -- it could be the way you've
13 implanted the mesh. You know, if it would have been
14 not laid nicely flat and for some reason it would be
15 compressed, that would be crumpling of mesh. So it
16 may not necessarily have to do with the tissue
17 contracture around the mesh post-healing.

18 Q. The inflammatory foreign body
19 reaction that triggers the scarification around the
20 mesh can lead to bunching or wrinkling of the mesh.
21 Correct?

22 A. Theoretically, yes.

23 Q. And the larger the inflammatory
24 response, the more contraction potentially.
25 Correct?

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1 MS. JONES: Object to the form.

2 THE WITNESS: Potentially correct.

3 BY MR. SLATER:

4 Q. And that could lead to bunching or
5 wrinkling of the mesh and exposure. Correct?

6 A. Theoretically correct.

7 Q. And what you wrote here on this table
8 that you attached to your clinical expert report is
9 that when the mesh degrades, that can lead to
10 bunching and wrinkling in the mesh and that can lead
11 to exposure. That's what you wrote on this
12 document. Correct?

13 MS. JONES: Object to the form.

14 THE WITNESS: Can you repeat and go
15 slow? Because I think you're jumping.

16 BY MR. SLATER:

17 Q. The FMEA -- rephrase.

18 This FMEA table in this line says
19 that degradation of mesh leads to bunching or
20 wrinkling in the mesh which can lead to exposure of
21 the mesh. That is what is documented there on the
22 table. Correct?

23 A. No.

24 Q. That's what the words say. Right?

25 A. But I explained to you clearly that

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1 is what can -- we theoretically think could happen.
2 We then try to mitigate for that hazard. And if it
3 would occur, it could result in a harm that could
4 result in a complication. But opposed to that,
5 you've got to look at what the frequency and the
6 severity of that complication would be. Okay? So
7 you have to look at the totality of this harms and
8 hazards table. So we are not, certainly not stating
9 that it degrades, that it crumbles and that it is a
10 complication. That is not what is written in this
11 table, and that's got to be very clear to the jury.

12 Q. What you told me earlier in this
13 deposition about this table was absolutely true.
14 Correct?

15 A. Yes.

16 MR. SLATER: No other questions.

17 MS. JONES: That's it.

18 THE VIDEOGRAPHER: This concludes
19 today's deposition. Going off the record. The time
20 is 5:30.

21 (Deposition adjourned at
22 approximately 5:30 p.m.)

23

24

25